

REMARKS

Prosecution of the instant case has been assumed by Foley & Lardner LLP. A Revocation and New Power of Attorney has been submitted. We request the Office please update the correspondence address and attorney docket number for this application.

Solely to advance prosecution of this application, claims 21 and 22 have been amended. New dependent claims 23-31 have been added. Applicant reserves the right to pursue the original claims, or claims of equal or greater scope in related applications.

Applicant would like to advise the Office, that the claims of a related European case directed to Applicant's laser system for photodamaging bacteria *in vivo*, has been deemed patentable by the European Patent Office (Application No. 04710257.9-2305). While this decision is not binding on the U.S.P.T.O., Applicant proffers such information since it may be material to the analysis of the prior art, which follows.

Applicant respectfully requests reconsideration and further examination of the subject application in light of the foregoing amendments and the following remarks.

Support for Claim Amendments

No new matter has been added by Applicant's amendments to the claims. Applicant has support for these in the specification and the claims as filed. Paragraph 28 of the specification describes invention as a dual wavelength-near infrared diode laser system, useful for bacterial destruction with minimal heat deposition at the site of irradiation. Specific exemplary near infrared wavelengths are provided throughout the specification and the original claims. Paragraph 31 of the specification indicates the wavelengths interact with an intracellular bacterial chromophore to photodamage (but not thermodamage) the bacteria, through acceleration of cellular damage pathways mediated by reactive oxygen species. Paragraph 33 and 34 indicate the lasers can be multiplexed, which allows the user to optimize the bacteriostatic and bacteriocidal effects of the phototherapeutic system. Paragraph 37 indicates the combined wavelengths of the invention use less energy than prior art approaches, where the goal in those references was thermolysis of bacteria.

Claim Rejections – 35 U.S.C. § 103

Parker and Rao

The Office has rejected claims 21 and 22 under 35 U.S.C. § 103(a) as being unpatentable over Parker et al. in combination with Rao et al., both of record. Applicant respectfully traverses this rejection and requests reconsideration for the following reasons.

For a proper rejection under 35 U.S.C. § 103(a), the cited references, when combined must teach or suggest each and every limitation in the claims at issue. Applicant does not concede that a skilled artisan would combine the Parker and Rao references, but in any event neither Parker et al. nor Rao et al., either alone or in combination, teach each element of the instant claims. Therefore, the claims are improperly rejected under 35 U.S.C. § 103(a) in view of Parker et al. and Rao et al.

Parker et al. is directed to and teaches the use of a blood constituent monitor including a light transmitter and a plurality of optical fibers positioned to transmit light to a body, and a light detector including a plurality of light detector fibers. See, page 5, lines 19-25. Parker et al. does not teach or suggest the application of laser energy at near infrared wavelength ranges as claimed by the Applicant in the subject application. Moreover, Parker et al. does not appreciate or recognize the advantages of applying near infrared wavelength ranges to bacteria. In fact there is not a single aspect of Parker et al. that teaches or suggests using his device on bacteria in a bacterial locale, or using light to photodamage bacteria. Parker et al. simply uses a light source and a detector to measure metabolic products of humans in human blood. The device of Parker et al. would not work to achieve Applicant's claimed process. The device would not be sufficient to cause bacterial photodamage through reactive oxygen species.

The Office cites Rao et al. as teaching "production of a wavelength range encompassing the entirety of Applicant's wavelength range with a titanium sapphire laser." Applicant points out that Rao et al. is directed to a three color laser for printing that can produce colors in the visible spectrum of light. Rao et al. does not teach therapeutic application of near infrared radiation, to a bacterial locale.

Rao et al. generates near IR frequencies, but these frequencies are then modulated to produce light with a blue spectrum. See, col. 2, lines 23-30. The 850-950 nm spectra generated by Rao et al. is simply an initial way to generate coherent light that is then frequency shifted to a desired range of 425-475 nm, which is then utilized as a blue beam for printing. Rao et al. actually teaches away from Applicant's claimed invention, as the nonvisible frequencies generated by the laser are not used themselves, but need to be frequency doubles to achieve a visible frequency. Light in this visible frequency range is not bacteriocidal. Rao et al. does not envision or discuss application of near infrared laser energy to humans. In fact, laser printers commonly have warning labels advising users to avoid beam exposure. Similarly, the device of Rao et al. does not indicate it can be used to damage bacteria. There is nothing in that reference that teaches or suggests using near infrared lasers to create photodamage to bacteria.

Thus, the combination of Parker and Rao does not teach (and seems to teach away from) each and every limitation recited in the claims, and therefore these references are an improper basis for a rejection of the claims under 35 U.S.C. § 103(a). Consequently, Applicant respectfully requests that the rejection of claims 21 and 22 under 35 U.S.C. § 103(a) in view of Parker and Rao be withdrawn and the claims allowed.

L'Esperence and Neumann

The Office has rejected claims 21 and 22 under 35 U.S.C. § 103(a) as being unpatentable over L'Esperence Jr. in combination with Neumann et al., both of record. Applicant does not concede that a skilled artisan would combine the L'Esperence Jr. and Neumann et al. references, for the reasons provided below. As such, Applicant respectfully traverses this rejection and requests reconsideration for the following reasons.

Applicant and his prior counsel had interviewed with the Examiner on March 25, 2008, and the interview summaries indicate agreement was reached concerning the claims, the wavelength ranges and the combinability of the L'Esperence Jr. and Neumann et al. references. Prior counsel's summary indicates agreement was reached in that Neumann et al. specifically teaches away from the *in vivo* use of wavelengths claimed by the Applicant.

Neumann et al. does not teach using lasers for *in vivo* phototherapy—to damage bacteria at a bacterial location. The Neumann et al. paper was written by five distinguished researchers, including doctoral degree holders and candidates, from the Departments of Physics, Molecular Biology, Chemical Engineering, and Electrical Engineering, at Princeton University and the Princeton Materials Institute at Princeton University. The five authors of the Neumann et al. published this paper in the well-respected Biophysical Journal published by the Biophysical Society. Neumann et al., by way of the article, informed skilled artisans to avoid use of laser energies *in vivo*, where the frequencies ranged in the photodamaging near infrared wavelengths. Accordingly, it is a wholly unexpected result that Applicant's claimed wavelengths are effective at power levels suitable for mammalian *in vivo* use.

Neumann et al., teaches the use of various near infrared wavelengths on bacteria isolated by so-called optical traps. The reference explores a range of wavelengths at extremely high power densities, e.g., on the order of $1 \times 10^7 \text{ W/cm}^2$, as typically used in such optical traps, which Applicant notes typically employ beam spot sizes on the order of a micron. The energy density of the laser systems described in Neumann et al. would not only be inappropriate for Applicant's purposes, but intolerable; as would be the beam spot sizes used, which would produce an energy density sufficient to create great thermal damage to the surrounding tissues at the treatment site. Accordingly, Neumann et al. fails to teach or suggest using laser radiation in two relatively narrow near infrared wavelength ranges, for damaging bacteria at an infected site without detrimental heat deposition or irreversible harm to a biological system including the infected site. Accordingly, Neumann et al. does not teach Applicant's invention, and the deficiencies of this reference are not cured by the addition of L'Esperance Jr.

L'Esperance Jr. teaches the use of a multi-beam laser system for application to an area of prospective surgical invasion of living tissue. Regarding the light produced by such a multi-beam laser system, L'Esperance teaches that such light: “(a) is of low-to-moderate intensity a tissue impingement and (b) is also of spectral wavelength that is preferably in the visible or in the infrared.” L'Esperance, col. 2, lines, 7-10. This specification encompasses any wavelength beginning at 400 nm (visible blue) out to 100,000 nm (the threshold of microwaves). This broad and general description in L'Esperance Jr. of expansive portions of the electromagnetic spectrum

fails to comprehend the significance, criticality, and unexpected results of the Applicant's claimed near infrared wavelength ranges at relatively low power levels, for producing photodamage in bacteria at an infected site. Likewise, L'Esperance Jr. teaches the use of exogenous agents, applied in advance of laser treatment, which are taken up by the microbes. Wavelength ranges are given, which exploit the photoabsorbtion profiles of these exogenous agents, where the agents themselves are chromophores that enhance the energy absorbtion and deposition within these microbial cells. This is not Applicant's invention. Applicant is not blasting bacterial cells with lasers to cause thermolysis. Applicant is using highly specific near infrared wavelengths to alter photobiologically, the biochemistry of the microbe through an intrinsic intracellular bacterial chromophore, which photodamages but not thermodamages the bacteria, through cellular damage pathways mediated by reactive oxygen species.

Applicant notes that MPEP § 716.02 and MPEP § 2144.05(III) set forth established law that holding that unexpected results arising from the criticality of a claimed subrange can provide for patentability of claims reciting the subrange. Such a claimed subrange can be patentable over any prior art which teaches broad ranges without comprehension of the uniqueness or unexpected results arising from the claimed subrange. As Applicant has stated in the subject application, the claimed near infrared wavelengths range of Applicant's invention are capable of treating bacteria in an infected site "with non-ionizing optical energy and minimal heat deposition." See, e.g., paragraph 13 of the subject application. Thus, L'Esperance Jr. teaches an enormously broad spectrum, very little of which could be used to produce the bacterial photodamage claimed by Applicant. L'Esperance fails to comprehend the uniqueness of the Applicant's claimed near infrared wavelengths and ranges, and does not teach or suggest the use of such specific and narrow wavelength ranges for producing photodamage via interaction with endogenous chromophores in bacteria at an infected site.

The Office cites a portion of *KSR International Co. v Teleflex Inc.*, 82 USPQ2d. 1385, 1397 (Sup. Ct., 2007) for the proposition that one of ordinary skill in the art would ignore the expressed direction of the authors of Neumann et al. (to avoid *in vivo* application of wavelengths around 870 nm and 930 nm) and "seeking to apply this pre-surgical sterilization method [of L'Esperance] would clearly look for wavelengths that are effective primarily against microbes

which would adversely affect the sterility of the site to be sterilized.” In asserting that a skilled artisan would ignore the teachings of the very references it cites against the Applicant, the Office has overstepped its boundaries, as relevant case law points out. “The Patent Office has the initial duty of supplying a factual basis for a rejection under 35 U.S.C. § 103. It may not, because it may doubt that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in its factual basis. In re Rice, 178 U.S.P.Q. 478 (C.C.P.A. 1973).”

Applicant submits that the Office has utilized hindsight reasoning in maintaining the obviousness rejection. The law is quite clear on the prohibition of this approach. The Office is reminded that “to imbue one of ordinary skill in the art with knowledge of the invention in suit, when no prior art reference or references of record convey or suggest that knowledge, is to fall victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher. W.L. Gore & Assoc. Inc., v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983).”

The combination of L’Esperence Jr. and Neumann et al. does not teach each and every limitation of the claims, and therefore the combination is an improper basis for a rejection of the claims under 35 U.S.C. § 103(a). Consequently, Applicant respectfully requests that the rejection of claims 21 and 22 under 35 U.S.C. § 103(a) in view of the L’Esperence Jr. and Neumann references be withdrawn and the claims allowed.

Provisional Claim Rejections – Double Patenting

The Office has provisionally rejected claims 21-22 of the application, under the judicially-created doctrine of obviousness-type double patenting, in view of Applicant’s U.S. Patent 7,255,560 and his applications: U.S.S.N. 10/961,796; U.S.S.N. 11/841,348; U.S.S.N. 11/848,517; U.S.S.N. 11/880,769; U.S.S.N. 11/930,941 and U.S.S.N. 12/995,887.

Applicant believes that the claims as amended obviate the double patenting rejection, and requests withdrawal of the same. The claims of 7,255,560 are directed to dental scaling equipment, and not to sterilization methods that reduce bacterial counts. Alternatively, Applicant requests this rejection be held in abeyance until the patentability of the instant claims is

established in view of the prior art rejections, and the patentability of the claims pending in the above cited applications is also resolved.

Conclusion

Applicant submits that the present application is in condition for allowance and such action is respectfully requested. The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application. The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741, reference docket number 093991-0019. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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